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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,795	01/03/2002	John A. Krueger	SPEC - 6137	6948

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,795	JOHN KRUEGER	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,669,882 to Pyles.

In regards to claim 1, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating n the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening.

3. Claims 1, 4, 5, 6, 9, 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,558,353 to Zohmann.

In regards to claims 1, 4, 5, 6, 9, 10 and 11, Zohmann discloses a biopsy system capable of obtaining a bone marrow sample including an outer cannula (70); a handle portion (60) coupled to the end of the outer cannula (Col. 7, lines 40 – 41); the outer cannula is adapted to removably accommodate a biopsy aspiration device (50) therein (Col. 7, lines 27 – 28). The aspiration device

includes an elongated cannula body having a proximal end (51), a distal tip (54) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body (Col. 6, line 45), the lumen terminating at a proximal opening (53) and terminating at a single laterally oriented distal opening immediately adjacent the distal tip; wherein the tip of the cannula body comprises an arcuate curved surface (Col. 6, lines 45 – 46) originating n the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. The proximal end of the aspiration device includes viewable indicia to indicate the position of the laterally oriented distal opening (Col. 7, lines 14 – 17). Zohmann discloses a stylet for removable insertion within the outer cannula (Col. 5, lines 49 – 52).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1 – 3, 6 – 8 and 11 - 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,478,751 to Krueger et al. in view of U.S. Patent No. 5,669,882 to Pyles.

In regards to claims 1 – 3, 6 – 8 and 11, Krueger et al. discloses a bone biopsy system having including an outer cannula (16); a handle portion (12) coupled to the end of the outer cannula; the outer cannula is adapted to removably accommodate a biopsy aspiration device (80) therein (Col. 7, lines 3 – 4). The aspiration device includes an elongated cannula body (82) having a proximal end (84), a distal tip (91) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal

opening (93) adjacent to the tip. The proximal end of the cannula body comprises a luer attachment for removable coupling of an aspiration source (Col. 6, lines 50 – 54). Krueger et al. discloses a stylet (14) for removable insertion within the outer cannula (16; Col. 4, lines 60 – 61). However, Krueger et al. fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening. However, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating n the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as taught by Krueger et al. to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Pyles in order to allow for rotation of the needle during use with a decreased chance of cutting the tissue of the patient (Col. 4, lines 5 – 8) and to improve directional control by the physician during rotation of the needle (Col. 4, lines 9 - 11).

In regards to claims 12 – 14, Krueger et al. discloses a method for obtaining a bone marrow sample from a morrow site in a patient including penetrating the cortex of a bone with an outer cannula having a stylet positioned within (Col. 7, lines 17 – 20), the distal portion of the stylet extending beyond the end of the outer cannula, until the distal end is surrounded by marrow; removing the stylet (Col. 7, line 22); inserting into the outer cannula a biopsy aspiration device such

that the distal tip of the aspiration device is extended into marrow (Col. 7, lines 25 – 26). Krueger et al. discloses attaching an aspiration source to the proximal end of the aspiration device and withdrawing a sample of marrow from the sampling site (Col. 7, lines 26 – 31). Krueger et al. discloses rotating the aspiration device within the outer cannula thereby repositioning the laterally oriented distal opening (Col. 7, lines 47 – 52). Krueger et al. discloses removing the aspiration device from the outer cannula and advancing the outer cannula into the bone to obtain a core sample (Col. 7, lines 55 – 59). Krueger et al. discloses the aspiration device including an elongated cannula body (82) having a proximal end (84), a distal tip (91) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (93) adjacent to the tip. However, Krueger et al. fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening. However, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as taught by Krueger et al. to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Pyles in order to allow for rotation of the needle during use with a decreased chance of cutting the tissue of the

patient (Col. 4, lines 5 – 8) and to improve directional control by the physician during rotation of the needle (Col. 4, lines 9 - 11).

Response to Arguments

Applicant's arguments filed 11/8/04 have been fully considered but they are not persuasive. In response to applicant's arguments regarding the rejections under 35 U.S.C. §102, the recitation "bone marrow biopsy aspiration device" in claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, a recitation with respect to the manner in which an apparatus is intended to be employed (i.e. for use as a bone marrow biopsy device) does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987). In response to applicant's arguments regarding the rejections under 35 U.S.C. §103, Applicant has asserted that the motivation provided by the Examiner is flawed. Applicant additionally asserts that is would be extremely undesirable to rotate a spinal epidural needle and to incorporate an epidural needle within a larger diameter outer cannula system and insert this into the spinal region to apply anesthesia. Claims 1 – 3, 6 – 8 and 11 – 14 are rejected as being unpatentable over Krueger et al. (6,478,751) in view of Pyles (5,669,882).

The Examiner is merely relying on Pyles (5,669,882) to provide a teaching of a needle having the claimed shaped. At no time has the Examiner suggested placing an epidural needle within a larger diameter outer cannula system and inserting this into the spinal region to apply anesthesia. To the contrary, the Examiner has presented a prima facie case of obviousness as why one having ordinary skill in the art would have been motivated to modify the aspiration needle as disclosed by Krueger et al. with the structure of the needle as disclosed by Pyles. Krueger et al. discloses a need for minimizing damage to the bone marrow tissue during sampling (Col. 1, lines 30 – 35) and rotating a needle within the bone marrow tissue (Col. 7, lines 48 – 51). Pyles teaches a rotating needle that minimizes damage to the tissue it is inserted into improves control by a physician while rotating (Col. 4, lines 5 – 11). The Examiner asserts that the motivation (i.e. to minimize damage to the tissue and to improve control for a physician) to modify the needle as disclosed by Krueger et al. as taught by Pyles is not flawed and maintains that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make such a modification based solely on the references themselves.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,807,277 to Swaim discloses a bone marrow biopsy system having a cannula body with a distal tip having an arcuate curved surface and a laterally oriented distal opening adjacent the tip

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

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